

REMARKS

Reconsideration and allowance of the subject application in view of the foregoing amendments and the following remarks is respectfully requested.

Claims 7-21 have been canceled. Claims 1-2 and 5 have been amended. No new claims have been added. Upon entry of this amendment, claims 1-6 are left pending. No new matter has been added.

Response to Election/Restriction

In response to the restriction requirement claims 7-21 have been canceled. Claims 1-2 and 5 have been amended to remove non-elected subject matter. Applicant affirms the election of claims 1-6. Applicant reserves the right to file a divisional to claim the non-elected subject matter.

Response to Rejections Under 35 USC 112, Second Paragraph

Claim 5 was rejected under 35 USC 112, second paragraph as being indefinite. In response to the Examiner's rejection under 35 USC 112, second paragraph. Claim 5 has been amended to add the phrase "wherein the monocyte derived cells are prepared according to the steps" which further limits claim 1 to a method of preparing said monocyte cells by performing steps a-d. Claim 1 is directed to a method of treatment including administration of monocyte derived cells and an effective amount of chemotherapy drugs to a patient.

Thus, it is respectfully suggested that the stated grounds for rejection under § 112 no longer apply to claim 5 and applicant requests that the rejection to this claim be withdrawn.

Response to Rejections Under 35 USC 103(a)

Claims 1, 2 and 4-6 were rejected under 35 USC 103(a) as obvious in light of Bartoleyns et al. (Immunobiology, 1996, vol. 195, pages 550-562).

The finding of *prima facie* obviousness was based on (1) the disclosure of Bartoleyns et al. of monocyte derived cells, also how to make mononuclear derived cells and Figure 1 in combination with the phrase “stimulation of the immune response against established tumor might only be successful when the tumor burden has been reduced to manageable proportions by prior surgery, chemo- or radiotherapy.”

In response to the Examiner’s rejection under 35 USC 103(a), claims 2 and 4-6 now depend from claim 1 which has been amended to add the phrase “with an interval between each administration being between 0 to 3 days.”

It was argued that it would be *prima facie* obvious to one having ordinary skill in the art to “[u]se monocyte derived cells in combination with other art-known chemotherapy with a reasonable expectation of success for cancer therapy since the efficacy of monocyte derived cells is taught in Bartoleyns et al. and suggests chemotherapy to reduce the tumor burden for stimulation of immune response by monocyte derived cells.”

In order for a claim to be properly rejected under § 103, a person having ordinary skill in the art at the time the invention was made must have a reasonable expectation of success. *In re Clinton*, 527 F.2d 1226, 1228 (C.C.P.A. 1976). A prior art suggestion for virtually endless experimentation is not a case of *prima facie* obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 471 (Fed. Cir. 1988).

It is respectfully suggested that Bartoleyns et al. does not provide a motivation to combine the treatment using monocyte derived cells and chemotherapy drugs with an interval of each administration between 0 to 3 days as with amended claim 1. Bartoleyns et al. teaches that “stimulation of the immune response against established tumor might only be successful when the tumor burden has been reduced to manageable proportions by prior surgery, chemo- or radiotherapy.” Therefore this teaching under Bartoleyns et al. suggests prior treatment of chemotherapy has already reduced tumor mass in advance of administration of monocyte derived cells. Respectively, the teachings of Bartoleyns et al. do not suggest a method of delivering monocyte derived cells and chemotherapy as disclosed with the method of amended claim 1.

Furthermore one would expect chemotherapy to limit growth or kill monocyte derived cells. Bartoleyns et al. does not suggest administration of monocyte derived cells

and chemotherapy within the timeframe of 0-3 days. Thus one would not have a reasonable expectation of success given the teachings of Bartoleyns et al. to combine treatment of monocyte derived cells and chemotherapy with the method as disclosed in amended claim 1.

Thus, it is respectfully suggested that the stated grounds for rejection under § 103 no longer apply to claims 1, 2 and 4-6 and applicant requests that the rejection to these claims be withdrawn.

Claim 3 was rejected under 35 U.S.C. 103(a) as obvious in light of Bartoleyns et al. (Immunobiology, 1996, vol. 195, pages 550-562) as applied to claim 1 above, and further in view of Gehl et al. (Seminars in Oncology, vol. 23, No. 6, Supp 15, December 1966, pages 35-38).

Respectively, Bartoleyns et al. does not disclose the method of amended claim 1 for the reasons set forth above.

Ghel et al. studies the effect of the combination doxorubicin and paclitaxel (Taxol; Bristol-Myers Squibb Company) on metastatic breast cancer. Taxol and doxorubicin are chemotherapy drugs well known in the art.

For the reasons set forth above a person skilled in the art would not have combined the teachings of Bartoleyns et al. with a chemotherapy drug such as Taxol in a manner consistent with amended claim 1. Claim 3 is dependent on claim 1 which has been amended to distinguish over the teachings of Bartoleyns et al. with the phrase "with an interval between each administration being between 0 to 3 days." Permitting patentability determinations based on an "obvious to try" test would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of 'research.' In re Tomlinson, 363 F.2d 928 (C.C.P.A. 1966).

Thus, it is respectfully suggested that the stated grounds for rejection under § 103 no longer apply to claim 3 and applicant requests that the rejection to this claim be withdrawn.

Filed concurrently herewith is a Notice of Appeal.

It is respectfully submitted that the claims have been put in condition for allowance. Notification to this effect is earnestly solicited. The Examiner is encouraged to contact the Applicants' undersigned attorney to discuss this matter if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

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